REMARKS/ARGUMENTS

Claims 1 – 23 remain in this application, with Claims 1 – 20 and 22 being withdrawn from further consideration. Claims 21 and 23 stand rejected.

Favorable reconsideration is respectfully requested in view of the following remarks.

REJECTION UNDER 35 U.S.C. § 102(b):

Claims 21 and 23 stand rejected as being anticipated by Unger et al. (5,244,460). In particular, the Examiner points to Col. 5, lines 22-33, of Unger et al. for allegedly teaching the concept of "a delivery instrument and a flowable agent causing the formation of lumens in the myocardium arranged to introduce particles at an entry site adjacent the cardiac tissue, generating a force external to the body to cause particles to pass through the contiguous tissue to target cardiac tissue without any mechanical means carrying said particles."

The Examiner states that the delivery of peptides constitutes a "flowable agent comprising a plurality of small particles." The Examiner goes on to state that these are blood vessel growth promoting peptides, particularly ones which foster myocardial blood vessel growth (column 1, lines 9-10). The Examiner states that since peptides are delivered to the coronary artery (by an impetus of a particle moving force in the form of being injected from a catheter), but treat heart tissue, the peptide particles pass from the entry situs without any mechanical means carrying the particles into the target cardiac tissue.

Independent claim 21, paragraph (c) (emphasis added), includes the limitations:

> imparting a particle-moving force through said instrument to said particles, said particle-moving force being generated external to the living being *to cause said particles to pass directly through contiguous tissue* [*i.e.*, non-target tissue] *to target cardiac tissue located remotely from said entry situs, said particles passing through said contiguous tissue* under the impetus of said particle-moving force without any mechanical means carrying said particles through said contiguous tissue, whereupon said particles directly enter said target cardiac tissue

In independent claim 21, the particles must pass through the contiguous tissue to arrive at the target tissue, resulting in localized delivery of treatment particles to the target cardiac tissue, with virtually no systemic delivery of the treatment particles. Delivery in Unger, et al. is directly into the blood system within a coronary artery, which then feeds the muscles of the heart. As the blood stream circulates, some of Unger et al.'s peptides flow past the heart muscles and are circulated systemically. While Unger's delivery occurs in the circulatory system immediately before traveling to their target tissue, the bolus of delivered peptides would then encounter the target tissue quickly, and could be an improvement over prior systemic delivery such as muscle injections. However, Unger is not relying upon the impetus provided by the injection to carry the delivered peptides to the cardiac tissue; rather, it is the natural action of the blood stream, combined with simple diffusion that is carrying Unger et al.'s peptides to their target tissue.

The Examiner sites column 5, lines 22-33 of Unger et al. for disclosing:

> a system comprising a delivery instrument and a flowable agent causing the formation of lumens arranged to introduce particles at an entry site adjacent the cardiac tissue, generating a force external to the body to cause particles to pass through the contiguous tissue to target cardiac tissue without any mechanical means carrying said particles.

It is noted that in the Unger et al. patent at col. 5, lines 34-39, Unger et al. continue to describe their delivery as occurring over the course of several hours (*e.g.*, 10 hours), to at least several seconds (*e.g.*, 10 seconds). In fact, continuous treatment for multiple days is within the scope of the Unger et al. invention. The present invention, as claimed, operates in an entirely different manner.

The Examiner pointed out in the Final Rejection that Unger et al. disclose delivery of peptides from the infusion port of catheter after an injection. The Examiner states that the injection is a particle moving force imparted to the particles. However, the Examiner appears to ignore the fact that the independent claims include limitations that the particles pass directly through contiguous tissue [i.e., non-target tissue] to target cardiac tissue located remotely from said entry situs without any mechanical means carrying said particles through said contiguous tissue.

In the last paragraph before his conclusion, the Examiner states that since Unger et al. deliver peptides to the coronary artery (by an impetus of a particle moving force, in the form of being injected from a catheter), but treat heart tissue, the peptide particles pass from the entry situs without any mechanical means

carrying the particles into the target cardiac tissue. Unger has not described the penetration of the particles carried by the impetus of the particle moving force through contiguous (non-target) tissue to arrive at the target tissue. The invention of Unger et al. infuses peptides into the coronary artery, which then feed the target tissue by movement of the blood stream.

Additionally, as stated previously, the Unger et al. patent is devoid of any disclosure of the use of flowable agent comprising a plurality of small particles which pass through tissue contiguous with an entry situs to target tissue. Rather, Unger et al. are simply performing repeated local delivery of peptides from a catheter inserted into heart vessels, as opposed to delivery of his peptides via oral delivery or systemic delivery by parenterial or intramuscular injections (See Unger at col. 7, lines 1-18). There is no indication of the use particles being delivered, let alone particles that pass through tissue to arrive at target tissue. The Office Action specifically refers to Col. 5, lines 22-33. However, step B of that section states that the delivery of the peptide is from an infusion port of a catheter. The delivery described by Unger et al. would therefore be the infusion of the blood vessels in which the infusion port of the catheter is located. There is no indication that the materials are being carried into and through tissue under the impetus of a particle moving force generated outside of the body as is set forth in the claims of the subject application.

It is therefore asserted that claim 21 is in condition for allowance. It is respectfully requested that the Examiner pass claim 21 to allowance. Claim 23 depends from independent claim 21 and therefore should also be allowable.

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance and claims 21 and 23 are allowable. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

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Please charge or credit our Account No. 03-0075 as necessary to effect entry and/or ensure consideration of this submission.